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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/733,767

12/12/2003

David Y. Chien

072121-0371

9347

27476

7590

03/21/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

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Emeryville, CA 94662-8097

EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

03/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/733,767	Applicant(s) CHIEN ET AL.	
	Examiner ANN Y. LAM	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 40-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10-18 and 22-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 6,924,107.

As to claim 1, Liu discloses a screening capture device for in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

an inlet (52, see col. 7, line 44 and fig. 3), (or alternatively, the claimed inlet is the inlet connected to the top tubing of the 4D chip in fig. 12) for blood collected from the collection needle (it is noted the needle is not being claimed as part of the screening capture device, nor is it disclosed in the specification as being part of the screening capture device, and thus, the claim is interpreted to mean that the screening capture device has an inlet that is capable of collecting blood from a collection needle);

a biochip unit (i.e., biochip 20, see col. 6, line 45 and fig. 1; or alternatively, the 4D chip disclosed in figs. 4 and 9, comprising a plurality of biochips, see also col. 8, lines 25-29) that captures a target agent or molecule from the blood; and

an outlet (54, see col. 7, line 44, and fig. 3) that drains the blood from the screening capture device to the collection duct (it is noted that the collection duct is not being claimed as part of the screening capture device nor is it disclosed in the specification as being part of the screening capture device, and thus the claim is interpreted to mean that the outlet is capable of draining blood from the screening capture device to a collection duct).

As to the limitations regarding the chambers of the in-line screening capture device having a cross-sectional area that is no smaller than that of the collection duct, the overflow tubings shown in figure 12 are considered to be collection ducts. (It is noted that there is no limitation regarding the size of the collection duct other than its size relative to the chamber, and thus the overflow tubing is deemed to be the collection duct.) While figures 3, 4 and 12 appear to show that overflow tubings (fig. 12) are the same size as or are no smaller than the chambers and outlets (figs. 3 and 4), there is no disclosure in the Liu that the drawings are drawn to scale or that the sizes of the elements of the device are drawn to scale relative to each other, and thus it cannot be inferred from the drawings that the overflow tubings are the same size as or are no smaller than the chambers and outlets. However, Liu does teach that the overflow tubings are pressure fitted in the top tier of the 3D biochip holder (col. 13, lines 49-50.) While this disclosure does not show that the chambers necessarily have a cross-sectional area that is no smaller than that of the overflow tubings, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

(MPEP 2144.05 IIA, citing *In re Aller*, 105 USPQ 233). In this case, Liu discloses the general conditions of the claim and the chambers having a cross-sectional area that is no smaller than that of the overflow tubings is within a workable range.

As to claim 2, the inlet (52) of the screening capture device is capable of being directly connected to a rear end of the collection needle (it is noted that the needle is not claimed as part of the claimed invention, i.e., the screening capture device).

As to claim 3, the inlet of the screening capture device is capable of being connected proximate to the collection needle. (It is noted that Examiner interprets the “collection duct” of claims 3 and 4 to *not* be part of the claimed screening capture device since it is not positively recited as being part of the screening capture device.)

As to claim 4, the inlet is capable of being connected, via a collection duct, proximate to the collection needle so that the temperature of the blood in the screening capture device is approximately 37 degrees Celsius.

As to claim 5, the biochip unit that comprises a first biochip and a second biochip that are sequentially arranged between the inlet and the outlet (see fig. 4 and 9, disclosing multiple biochips forming a 4D chip; and fig. 11 and 12, showing that the 4D chip is connected to tubings at the top and bottom; and see col. 9, lines 13-21, disclosing an embodiment wherein the biochips are fluidly connected and sample flows in a single direction). (The claimed inlet is the inlet connected to the top tubing of the 4D chip in fig. 12 and the claimed outlet is the outlet connected to the lower tubing of the 4D chip in fig. 12).

As to claim 6, the first biochip and the second biochip are arranged in a parallel stacked fashion (see fig. 4 and 12).

As to claim 10, the screening capture device is capable of capturing a target agent or molecule that comprises at least one protein, nucleic acid molecule or fragment thereof indicative of or specific for a disease in a subject or an infectious agent. (The Office notes that Applicant has not recited any further structural limitations in claim 10, nor how the target agent is captured or what structures allow for capturing the target agent.)

As to claim 11, the screening capture device is capable of capturing a target agent that is an antibody or antigen.

As to claim 12, the first biochip is capable of being a nucleic acid amplification technique (NAT) biochip designed to run multiple tests on the first chip. (The Office notes that Applicant has not recited any further structural limitations in claim 12, nor what structures allow for the nucleic acid amplification or multiple testing.)

As to claim 13, the first biochip is capable of capturing at least one infectious organism or cell containing a targeted nucleic acid molecule. (Applicant has not recited any structural limitations that allow for the capturing.)

As to claim 14, the infectious organism can be a virus or bacteria. (Applicant has not recited any structural limitations that allow for capturing of the virus or bacteria.)

As to claims 15 and 16, the second biochip is capable of performing multiple immunoassays and can capture targeted antigens and antibodies. (Applicant has not recited structural limitations that allow for the immunoassay intended use.)

As to claim 17, the first and second biochip are considered low density biochips (col. 6, line 61).

As to claim 18, Liu does not show microarrays arranged along the length of the biochip in the direction of blood flow. However, Liu does disclose that the inside walls of the chips are coated with a probe, e.g., DNA, peptide, antibody, etc. (col. 8, lines 45-49; and col. 13, lines 30-33 and 42-44.) Liu also discloses that the biochip for example can be composed of 4 regions each having 96 capillary channels thereby having 96 features per quadrant, and that in such a biochip, there are numerous arrangements for coating an assaying the biochips. For example the 96 replications can correspond to the geometry of a 96-well microtiter plate, allowing for assaying 96 bio-samples in parallel (col. 14, lines 13-15.) Liu further disclose that the capillaries are arranged in an array though many different configurations may also be used. It is also disclosed that the dimensions (e.g., width, length and thickness) and configurations of the plate (20) (which forms the biochip) and the capillaries (50) may vary widely. Liu disclose an embodiment in figures 1 and 3 but notes that the 3D biochip may be configured in many different orientations (col. 7, lines 7-10.)

Given the suggestions by Liu of making the biochip and capillaries in various dimensions and configurations, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a biochip having dimensions such that the capillary channels run along the length, i.e., the longest dimension, of the biochip. In other words, providing a biochip in which the thickness from inlet to outlet of the biochip is increased such that it is actually the length of the biochip, and providing capillaries

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such that they run along the length of the biochip in the direction of blood flow, would have required only ordinary skills in the art as such dimensions and configuration would also perform the functions of the Liu invention and Liu also specifically disclose that various dimensions and configurations may be used in forming the biochip and capillaries. (Such a biochip would have microarrays arranged along the length of the biochip in the direction of blood flow because each capillary with probes attached is equivalent to a microarray as described in Applicant's specification, paragraph 47.)

As to claim 22, the inlet and outlet are capable of being sealed when the screening capture device is removed from the collection needle and the collection duct. (Applicant has not claimed any structural limitations that seal the inlet or outlet).

As to claim 23, the top biochip (see fig. 11) is considered to be a lid and it is capable of being robotically removed. (Applicant has not claimed any structural element to the lid.)

As to claim 24, Liu discloses a screening system for in-line screening of blood collected from a donor using a collection needle connected by a collection duct to a collection bag, comprising:

a screening capture device for in-line attachment between the collection needle and the collection duct, the screening capture device comprising:

an inlet for blood collected from the collection needle (52, see col. 7, line 44 and fig. 3), (or alternatively, the claimed inlet is the inlet connected to the top tubing of the 4D chip in fig. 12) for blood collected from the collection needle (it is noted the needle is not being claimed as part of the screening capture device, nor is it disclosed in the

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specification as being part of the screening capture device, and thus, the claim is interpreted to mean that the screening capture device has an inlet that is capable of collecting blood from a collection needle);

a biochip unit (i.e., biochip 20, see col. 6, line 45 and fig. 1; or alternatively, the 4D chip disclosed in figs. 4 and 9, comprising a plurality of biochips, see also col. 8, lines 25-29) that captures a target agent or molecule from the blood; and

an outlet (54, see col. 7, line 44, and fig. 3) that drains the blood from the screening capture device to the collection duct (it is noted that the collection duct is not being claimed as part of the screening capture device nor is it disclosed in the specification as being part of the screening capture device, and thus the claim is interpreted to mean that the outlet is capable of draining blood from the screening capture device to a collection duct);

and at least one biochip processor (i.e., one of the chambers, 60) for detecting at least one captured target agent or molecule.

As to the limitations regarding the chambers of the in-line screening capture device having a cross-sectional area that is no smaller than that of the collection duct, see discussion of claim 1 above.

As to claim 25, the biochip processor is capable of amplifying said target agent or molecule.

As to claim 26, the biochip processor is considered to be a sealed disposable unit (see fig. 3), (the processor is considered to be capable of being disposed) having a

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nucleic acid amplification technique (NAT) portion for processing a first biochip and an immunoassay portion for processing a second biochip.

As to claim 27, the system is capable of capturing a nucleic acid molecule (it is noted that Applicant has not recited how the nucleic acid molecule is captured), and the NAT portion comprises:

- a biochip holder (any portion of "biochip holder" in fig. 12);
- at least one reservoir (any of chambers 60) for holding a sample;
- at least one amplification reaction chamber (any of the other chambers 60) connected to the reservoir (see fig. 3); and
- at least one detection component (capillary 50) connected to the amplification reaction chamber. (It is noted that Applicant has not recited any structural limitations of the detection component.)

As to the limitations regarding the chambers of the in-line screening capture device having a cross-sectional area that is no smaller than that of the collection duct, see discussion of claim 1 above.

As to claim 28, the device further comprises:

- at least one reagent container (any of the other chambers 60, see fig. 3) connected to the reservoir; and at least one reagent container (any of the other chambers 60, see fig. 3) connected to the reaction chamber.

As to claim 29, the NAT portion further comprises the first biochip (fig. 3) held in the biochip holder (any portion of "biochip holder" in fig. 11).

As to claim 30, the first biochip is held such that a surface is capable of containing analytes in contact with at least one elution and lysing buffer.

As to claim 31, the detection component is at least one microfluidity chamber (any of the chambers 60, see fig. 3).

As to claim 32, there are more than one biochip processors (see the plurality of chambers 60 in fig. 3).

As to claim 33, system is capable of capturing a target antibody or a target antigen, and the immunoassay portion comprises:

- a biochip holder (any other portion of "biochip holder" in fig. 11);

- at least one reservoir for holding a sample (one of the chambers 60 in fig. 3 in one of the biochips in fig. 11);

- at least one reaction chamber (one of the other chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reservoir; and

- at least one detection component (one of the other chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reaction chamber.

As to claim 34, the immunoassay portion further comprises:

- at least one reagent container (one of the chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reservoir; and

- at least one reagent container (one of the other chambers 60 in fig. 3 in one of the biochips in fig. 11) connected to the reaction chamber.

As to claim 35, the immunoassay portion further comprises: the second biochip held in the biochip holder (one of the biochips in the biochip holder in fig. 11).

As to claim 36, the second biochip is capable of being held such that analytes are in contact with at least one buffer.

As to claim 37, the detection component is at least one microfluidity chamber (one of the chambers 60 in fig. 3).

As to claim 38, there is at least two reaction chambers (60, fig. 3), one for the detection of a target antibody and one for the detection of a target antigen.

As to claim 39, each reaction chamber is connected to at least one detection component comprising at least one microfluidity chamber (one of the other chambers 60 in fig. 3).

Claims 7-9, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 6,924,107, in view of Narang et al., 6,020,209.

Liu discloses the invention substantially as claimed (see above).

As to claim 19, Liu does not disclose that the first and second biochips comprise covalently attached analytes. However, Narang et al. teach a chip with immobilized antibody molecules for immunoassay purposes (col. 5, line 60 – col. 6, line 19; and col. 4, lines 62-67.) Narang et al. also teach that the antibodies are immobilized by covalent bonding (col. 5, lines 12-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize antibody molecules as taught by Narang et al. in the Liu biochip because Narang et al. teach that immobilized antibody molecules in a chip allow for performing immunoassays. The analyte (antigen) is at the

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least indirectly covalently bound to the biochip because the antibody is disclosed to be covalently bound to the chip (col. 5, line 12-14).

As to claim 21, Liu also does not disclose that the device further comprises an anti-backflow device that prevents the blood from flowing back towards the inlet. However Narang et al. teach a biochip with valves and pumps for fluid control and still produce a small, lightweight flow immunosensor (col. 5, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a valve as taught by Narang et al. in the Liu biochip because Narang et al. teach that a valve, in addition to pumps, allow for fluid control, as would be desirable in performing immunoassays. The valve is considered to be an anti-backflow device. (Applicant has not recited any structural limitations relating to the anti-backflow device.)

As to claim 7, while Liu does not teach that the dimensions of the screening capture device are such that a flow rate of blood flowing through the screening capture device is equal to the flow rate of the collected blood in the absence of the screening capture device, Narang et al. however teach use of pumps for fluid control and still produce a small, lightweight flow immunosensor (col. 5, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pump as taught by Narang et al. in the Liu biochip because Narang et al. teach that a pump allows for fluid control, as would be desirable for convenience and for performing immunoassays. With the Liu biochip modified by Narang et al. to provide for a pump, the dimensions of the capillaries (50) in the Liu biochip is capable of allowing a flow rate

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as recited by Applicant. (The Office notes that Applicant's claim do not exclude this embodiment.)

As to claim 8, Liu does not teach that the dimensions of the screening capture device are such that the flow rate of blood flowing through the screening capture device is about 450 ml per 10 minutes. However, with the Liu biochip modified by Narang et al. to provide for a pump, the dimensions of the capillaries (50) in the Liu biochip is capable of allowing a flow rate as recited by Applicant.

As to claim 9, Liu does not teach that the dimensions of the inlet, the outlet, a surface area of biochips in the biochip unit, and the screening capture device case are such that the collected blood maintains a constant flow rate through the screening capture device. However, with the Liu biochip modified by Narang et al. to provide for a pump, the dimensions of the capillaries (50) in the Liu biochip is capable of allowing a flow rate as recited by Applicant.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu, 6,924,107, in view of Bashir et al., US 2001/0053535, and further in view of Yamanishi et al., US 2003/0134416.

Liu discloses the invention substantially as claimed (see above), except for the outlet including a funnel and a filter.

However, Bashir et al. teach separating of contaminants from a fluid sample on the biosensor chip by trapping the material of interest, that may be immobilized on

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carrier elements, in a detection chamber on a biosensor chip while flushing remaining portions of the fluid sample from the chamber. Bashir et al. teach that this trapping of the material of interest in a detection chamber serves in part to concentrate the material of interest and thus enhance the sensitivity of the detection technique. Bashir et al. teach that the trapping may be implemented in part by providing a filter barrier or retention structure at an outlet of the detection chamber (paragraph [0025]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a filter barrier as taught by Bashir et al. in the Liu biochip for use as a detection chamber as taught by Bashir et al. because Bashir et al. teach that the filter provides the advantage of concentrating the material of interest and allowing for detection and also enhancing the sensitivity of the detection technique.

Moreover, Yamanishi et al. teach that in fabricating filter slots, the slot can be tapered so that the sample goes through the narrow-width side first and then filtered cells exit at the wide-width side of the slot so that trapping of cells are avoided as they are being filtered. Yamanishi et al. also teach that the orientation of the filter can be such that the wide-width side of the filter slots faces the sample (paragraph [0199]). (The tapered slot is considered by the Office to be a funnel because it has the shape of a funnel.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a tapered slot as taught by Yamanishi et al. in the Liu invention as modified by Bashir et al. providing a filter because Yamanishi et al. teach that the tapered slot provides the benefit of preventing trapping of materials such as cells as they are being filtered, as would be desirable for preventing a clog in the device.

Response to Arguments

Applicants' arguments filed December 21, 2007 have been fully considered.

The claims objections and 112, second paragraph rejection made in the previous Office action have been withdrawn in view of Applicant's amendment and/or comments.

Applicant's arguments regarding the prior art however are not persuasive.

Applicant argues that the claimed invention requires that the chambers through which blood flows are designed to have a cross-sectional area that is no smaller than that of the collection duct, in order to minimize any reduction in blood flow through the claimed device. Applicant further states that in contrast the device of Liu is designed so that the volume flowing the device is reduced to control consistent reduced flow through the device, pointing to column 8, lines 58-63, column 9, lines 60-63, column 10, lines 21-22 and column 12, lines 1-4. Applicant asserts that Liu teaches away a device with chambers having "a cross-sectional area that is no smaller than that of the collection duct."

Examiner agrees that the device of Liu is designed to reduce the volume flowing through the device. However, this teaching does not require or suggest that the overflow tube, which is considered by Examiner to be equivalent to the claimed collection duct, be smaller than the chamber. Column 8, lines 58-63, cited by Applicant only states that

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due to the small sizes of the capillaries and the channels and the small amount of reagent solution, precise control over the flow rate of the reagent probe solution is desirable. Column 9, lines 60-63, cited by Applicant discloses that the use of small diameter capillaries with controlled flow of the probe solution further increases effective concentration of the complementary RNA strands. Column 10, lines 21-22, cited by Applicant mentions a volume-reducing liquid arrayer. Column 12, lines 1-4, cited by Applicant discloses that the smaller diameter of the second arrayer capillaries reduces the volume per unit length of the solution in the capillary and provides more accurate and easier regulated volumetric control over the flow of the biosample solution from the reservoir to the biochip. Examiner notes however that none of these disclosures relate to the overflow tube (equivalent to the claimed collection duct) or suggest that the overflow tube must be smaller than the capillaries to which it is fluidly connected.

Applicant also points out that the specification on page 8, last line states that the device is designed so that the rate of blood flowing through the device is equal the flow rate of the collected blood in absence of the device. It is asserted by Applicant that Liu does not teach this but rather teaches use of small capillaries to reduce and control flow rates. Applicant argues that it is not obvious to modify the teachings of Liu in a manner that would increase the flow rate through the Liu device, namely by incorporating a chamber having a cross-sectional area that is no smaller than that of the collection duct.

Examiner notes that the teachings by Liu regarding use of small capillaries to reduce and control flow rates relates to the capillaries reducing the area occupied by the well array (col. 11, lines 4-6) and that Liu teaches that the reduction in the arrayer

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capillary array area may be accomplished with a single arrayer block (col. 11, lines 28-33), and that reducing the arrayer capillary array area may be alternatively accomplished with multiple arrayer blocks, wherein each arrayer block reduces the area occupied by a particular subset of the first arrayer capillary array (col. 11, lines 34-40). In short, the reduction in volume is accomplished by the small size of the capillaries themselves in one arrayer block, or by reducing the size of the capillaries in each subsequent arrayer block. Examiner emphasizes that while a disclosed embodiment includes capillaries that are smaller in each subsequent arrayer block, the Liu invention also includes an embodiment wherein only one arrayer block is needed to reduce the area occupied by the well array. Regarding either embodiment, there is no mentioning that the overflow tube (which Examiner has asserted to be equivalent to Applicant's claimed collection duct) should be smaller than the capillaries, nor would an overflow tube that is the same size or slightly larger than the capillaries to which it is fluidly connected increase the flow rate such that it would defeat the Liu purpose of reducing and controlling flow rate by using capillaries to reduce the area occupied by the well array.

Applicant further argues that the claimed device is suitable for in-line screening of blood while the Liu device is not. Applicant asserts that Liu discloses no pumping mechanism and no system for drawing blood from a needle inserted into a donor, through a collection duct and screening capture device, and into a blood collection container, and Liu does not even mention blood. It is argued by Applicant that modifying the Liu device into a high flow blood sampling device would render the Liu device

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unsatisfactory for its intended purpose, i.e., high throughput screening of prepared sample.

Examiner notes however that the needle and any tubing or duct connecting the needle to the biochip system are not claimed and thus these structural elements need not be disclosed by Liu. Thus, the limitations regarding connection to a needle is interpreted to be an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Liu device (e.g., via the tubings connected to the biochips) is capable of being attached to a needle and thus meets the claim. Moreover, Liue does disclose a pumping mechanism for controlling flow (col. 12, lines 47-50), and the Liu device is capable of screening blood since it is capable of allowing flow of blood into the device for screening.

As to claim 18, Applicant has put the claim in independent form as it was indicated in the previous Office action as having allowable subject matter. However, upon reconsideration, Examiner finds that claim 18 is unpatentable over Liu as discussed in the rejection of claim 18 above. Because the rejection of claim 18 is new, the present Office action is made nonfinal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641

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